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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

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EXAMINER

WEBB, JAMISUE A

ART UNIT PAPER NUMBER

3761

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

Jamisue A. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2002.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31-33,36 and 41-53 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 31-33,36 and 41-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 July 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the leg cuff and the skin care composition disposed on the topsheet in a plurality of stripes that are separated by a plurality of stripes having no skin care composition must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant, in the specification, has not disclosed that the article comprises from about 0.001% to about 30% by weight of the protease inhibitor.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 31-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With respect to Claim 31: the phrase “wherein the protease inhibitor is 4-(2-aminoethyl)-benzenesulfonylfluoride hydrochloride, hexamidine and its salts, or pentamidine and its salts” is indefinite. The claim claims “a” protease inhibitor, meaning one protease inhibitor, yet the phrase above states it can be “hexamidine and its salts” or “pentamidine and its salts”, both of which or plural.

7. With respect to Claim 42: the applicant in Claim 41, claims the use of a delivery system for the protease inhibitor. Claim 42 discloses the delivery system is a skin care composition that comprises a protease inhibitor. Does this mean that there are two protease inhibitors, one that is in the skin care composition that is the delivery system, and the other that the delivery system is for?

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 31-33, 36, and 41-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of Kasahara et al. (JP 04-182,423).

10. With respect to Claims 31-33, 36, 41-44, 49, 51 and 52: Roe teaches a diaper containing a topsheet coated with a semisolid lotion and immobilizing agent. The lotion may be applied to the topsheet non-uniformly where portions of the surface do not have any lotion on it.

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Roe however fails to provide the lotion containing a protease inhibitor. Kasahara et al. teaches protease inhibitors in the form of a lotion or emulsion where the inhibitors include benzamidine and derivatives thereof, (page 6, number (3)). It is the examiner's position that benzamidine is an equivalent structure to pentamidine, functional wise, due to the fact that the active or functional group of the pentamidine is the benzamidine structure. In other words, benzamidine and pentamidine have the benzene ring with a carbon bonded to a double bonded NH group and a single bonded NH₂ group, the only difference is pentamidine has two benzene rings with the NH groups, where as benzamidine, only has one, therefore it is the examiner's position that the groups are functionally similar. The examiner considers IC₅₀ to be an inherent property in the protease inhibitor itself. Due to the fact that Kasahara discloses many claimed protease inhibitor, then the examiner considers Kasahara to disclose all the claimed IC values.

It would have been obvious to one skilled in the art at the time the invention was made to use the protease inhibitor composition of Kasahara on the topsheet of Roe, to reduce skin irritation and prevent diaper rash. (see Kasahara page 5).

11. With respect to Claims 45, 46 and 50: Roe discloses the skin care composition being on the topsheet, therefore it will be transferred onto the skin of the wearer by either heat or pressure.

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) and Kasahara et al. (JP 04-182,423) in further view of VanRijswijck et al. (6,120,488).

13. Roe and Kasahara, as disclosed above for claim 31, disclose the use of the skin care composition being disposed on the topsheet, but fails to disclose the skin care composition being disposed in stripes on the topsheet. VanRijswijck discloses the use of a skin care composition disposed on the topsheet in a plurality of stripes (column 21, lines 46-65). It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to have the skin care composition of Roe, be disposed in stripes, as disclosed by VanRijswijck, in order to provide unique skin care benefits to different areas of the wearer. (See VanRijswijck column 21).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Caldwell et al. (5,856,245) discloses the use of a barrier web that has pentamidine incorporated into it.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579. The examiner can normally be reached on M-F (7:30 - 4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703)308-2262. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw *SW*
June 4, 2002

GKD
GLENN K. DAWSON
PRIMARY EXAMINER